**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC., and TEVA NEUROSCIENCE, INC.,<br><br>Defendants. | Civil Action No. 20-11548<br><br>**Leave to File Granted on April 24, 2023** |

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

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## I. INTRODUCTION

Two recent Court of Appeals decisions make clear that the government's case is based on a fundamental misapplication of the law of causation for False Claims Act ("FCA") cases premised on the Anti-Kickback Statute ("AKS"). Under the plain language of the AKS, the government must prove that a kickback was the "but for" cause of the particular false claim—*i.e.*, that a prescriber would not have prescribed the product, or that the patient would not have used it, in the absence of the kickback. This is an "essential element." It must be proven. It cannot be presumed, as the government would have it here. The government's proof has not identified a single claim that would not have been submitted for reimbursement to Medicare in the absence of Teva's[1] donations to patient assistance programs ("PAPs"). That is because Teva's donations simply made it easier for patients to access the medication that a doctor had already prescribed. Thus, the government's case fails for lack of proof of causation.

In addition, the government cannot prove the essential element of scienter. The undisputed evidence establishes that Teva acted on an objectively reasonable interpretation of the AKS and the OIG's ambiguous administrative guidance. No witness—including the key witness cited by the government in its Complaint, Edward Hensley—has testified that he or she understood at the time the donations were being made that Teva's conduct was unlawful, and no authoritative guidance warned Teva away from its interpretation. On the contrary, under the plain language of that guidance—and according to the very recent testimony of one of its drafters—a manufacturer could donate with the ***intent*** to benefit patients on one's own drug without necessarily violating the AKS. Under these circumstances, Teva did not act with the

[1] Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Neuroscience, Inc. ("Teva Neuroscience") (collectively, "Teva").

requisite scienter—*i.e.*, "willfully" under the AKS or with "knowledge," "deliberate ignorance," or "reckless disregard" under the FCA.

For these reasons and those stated below, summary judgment should be granted in favor of Teva and against the government on all counts.

## II. FACTUAL BACKGROUND

The government contends that Teva's donations to two charitable patient assistance foundations were kickbacks resulting in federally reimbursable purchases of Teva's multiple sclerosis ("MS") treatment, Copaxone. In reality, the donations were exactly what the government wanted and needed pharmaceutical manufacturers to provide. Without them, financially needy Medicare patients would need to seek out alternative sources of funding in an effort to afford the treatment that their doctors clinically and independently determined was medically necessary. Indeed, there is no dispute that each Copaxone prescription at issue was both medically necessary and resulted from a physician's independent medical judgment.

### A. Medicare Part D.

In 2006, Medicare Part D prescription drug coverage went into effect. 42 U.S.C. § 1395w-101(a)(2). The program had a significant shortcoming: it did not subsidize the full cost of prescription drugs. (Teva's Rule 56.1 Statement of Material Facts in Support of Motion for Summary Judgment ("SOF") ¶¶ 1-5.)[2]

On November 22, 2005, OIG issued the Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees that recognized the need for continued financial support by the pharmaceutical industry to fill the Part D "coverage gap." *See* 70 Fed. Reg. 70623, 70626

[2] Where used, "Ex." refers to an exhibit described in and attached to the accompanying SOF, including the portions of the exhibits identified in the corresponding paragraph of the SOF.

(Nov. 22, 2005) ("2005 SAB"). The OIG acknowledged that "[p]atient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means" and that the passage of Medicare Part D did not obviate the need for that safety net. *Id.* at 70626. The OIG thus notified the public "that pharmaceutical manufacturers can ***effectively contribute to the pharmaceutical safety net by making cash donations to independent***, bona fide charitable assistance programs." *Id.* (emphasis added).

While the 2005 SAB is a policy document and not binding law,[3] it makes clear there was no proscription against a manufacturer donating to a fund that supported its own products, or even a fund that supported ***only*** its own products. 2005 SAB, 70 Fed. Reg. at 70627. As the OIG's primary author of the 2014 supplement to the 2005 SAB, Heather Westphal, recently testified, [redacted] (SOF ¶ 25.) Instead, [redacted]

[redacted]

(*Id*.) (emphasis added, objections omitted).

[redacted]

[3] *See, e.g.*, *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015); *U.S. ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. CV 02-2964, 2020 WL 4260797, at *8 (E.D. Pa. July 24, 2020).

(*Id*.) (emphasis added, objections omitted).

(*Id*.) (emphasis added, objections omitted).

**B. Teva's Charitable Support.**

**1. Teva's Copaxone Treats MS, A Life-Altering Disease.**

MS is a disease of the brain and spinal cord that causes severe disability. The majority of those who suffer from MS are women. (SOF ¶ 30.) Copaxone is an injectable medicine used to treat relapsing forms of MS in adults. (*Id*. ¶¶ 31, 33.) It is a disease modifying therapy ("DMT") because MS has no cure, and the goal of treatment is to prevent the accumulation of irreversible neurological damage, reduce relapses, and delay the onset of secondary progressive relapses. (*Id*. ¶¶ 27-29.) MS can result in severe and permanent cognitive and physical disabilities. (*Id.* ¶ 29.) The standard of care for a patient with an MS diagnosis is treatment with a DMT. (*Id*. ¶ 32.) The undisputed evidence demonstrates that, during the entirety of relevant period, patients faced similar out-of-pocket costs to Copaxone for a variety of different manufacturers' MS DMTs. (*Id*. ¶ 38.) It is further undisputed that Copaxone is and was the only DMT safe for pregnant women and women trying to conceive. (SOF ¶ 40.)

**2. Teva's Shared Solutions Program Helped Patients Investigate Benefits and Referred Them to Third-Party Patient Assistance Hubs.**

Teva's Shared Solutions program was an internal team that Teva created to provide

patients with educational resources, injection training, proactive outreach by medical practitioners, and benefits investigation services. (*Id*. ¶¶ 41-44.) If a patient had or was eligible for Medicare Part D and needed financial assistance accessing their Copaxone prescription, Shared Solutions referred the patient to a third-party vendor that provided benefits investigation services and assisted patients with, among other things, applying for copay assistance from 501(c)(3) patient assistance foundations. (*Id*. ¶ 43.) From October 2006 through 2014, the vendor (or "hub") with which Teva contracted for benefits investigation services, and to whom Teva referred financially needy Copaxone patients, was Advanced Care Scripts, Inc. ("ACS"). (*Id*. ¶ 47.) From February 2015 through at least the rest of 2017, Teva contracted with AssistRx, which performed the services previously handled by ACS. (*Id*. ¶ 48.)

**C. CDF and TAF Were Independent of the Manufacturers that Donated to Them.**

The charitable foundations at issue are the Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"). *See* Compl. (ECF No. 1). The OIG concluded, in 2006 and 2010, respectively, that the structure of CDF's and TAF's patient assistance programs interposed an independent, bona fide charitable organization between donors and beneficiaries in a manner that would insulate beneficiary decision-making from information attributing their funding source to any particular donor. (SOF ¶ 16.)

The independence of the charities is reflected in multiple, undisputed ways. CDF and TAF at all times retained full control and discretion regarding the distribution of donations within the MS funds. (*Id*. ¶¶ 58, 85.) According to TAF's Co-Executive Director Edward Hensley, TAF, for instance, had "absolute, independent, and autonomous" discretion as to use of manufacturer donations for grants." (*Id*. ¶ 85.) Thus, donors' contributions to CDF and TAF were "pooled" together for a particular disease state fund before ever being allocated to a patient,

and patients who qualified for funding kept that funding even if they switched their MS treatment. (*Id*. ¶¶ 60, 63, 86, 87.) Among others, TAF's Mr. Hensley testified that Copaxone patients did not have to remain on the treatment as a condition of receiving funding. (*Id*. ¶ 86.) The same was true at CDF. (*Id*. ¶ 63.)

Further, CDF and TAF applied objective eligibility criteria without influence and input from donors, the patient's choice of provider, practitioner, insurer, insurance plan, supplier, test, or product. (*Id*. ¶¶ 57, 85.) Both CDF and TAF processed patient applications on a first-come, first-served basis. (*Id*. ¶¶ 62, 86.) When funding was available, CDF and TAF awarded grants to eligible patients regardless of the MS medication they had been prescribed. (*Id*. ¶¶ 63, 89.) It is further undisputed that Copaxone was one of many MS drugs covered by donations received. (*Id*. ¶¶ 64, 67, 82, 90.)

Finally, and highly significant to the OIG views of the appropriateness of donations, there is no evidence that CDF or TAF advised patients of the identity of the donors supporting their grants. Indeed, evidence in the record shows that did not take place. (*Id*. ¶¶ 61, 88.)

From 2006 to 2014, Teva donated money to CDF's MS fund; from 2009 to 2018, Teva donated to TAF's MS fund. (*Id*. ¶ 45.) During the years in which Teva donated to CDF and TAF, Teva's donations vastly exceeded the charities' support for patients on Copaxone—by more than ***90 million dollars***. (*Id*. ¶¶ 67, 90; Ex. 29, P. Ellis Rebuttal Rpt. Table 18R.)

### D. The OIG SABs Do Not Address Third-Party Hubs or the Practices the Government Contends are Problematic In this Case.

The 2005 SAB does not define what conduct would necessarily constitute a violation of the AKS; rather, it provides an illustrative list of the types of "safeguards" the OIG had in mind that, if followed, "should raise few, if any," AKS "concerns": (i) the pharmaceutical manufacturer exerts no *direct or indirect influence or control* over the charity; (ii) the charity

awards assistance in a *truly independent manner that severs any link* between the manufacturer's funding and the beneficiary (*i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer*); (iii) the charity awards assistance *without regard to the manufacturer's interests and without regard to the beneficiary's choice of product*, among other things; (iv) the charity provides assistance based upon *a reasonable, verifiable, and uniform measure of financial need* that is consistently applied; and (iv) the manufacturer does not solicit or receive *data from the charity* that would facilitate it in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products. *Id*. at 70626. The Guidance summarizes the factors and its expectations as follows:

> Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices.

*Id*.

Of particular relevance here, the 2005 SAB specifically condoned a manufacturer donating to a fund that covered its own product, and even a fund that covered ***only*** its own product. *See* 2005 SAB at 70627 n. 19. That is because the OIG concluded that the involvement of an independent charity "sever[s] the nexus between the patient subsidies and the manufacturer." 2005 SAB at 70624 n. 3; SOF ¶ 16; Ex. 5, 2006 CDF Opinion at 7 ("[CDF] awards assistance in a truly independent manner that severs any link between donors and beneficiaries."); Ex. 6, 2010 TAF Opinion at 6 (similar).

The 2005 SAB did not, however, address the extent to which manufacturers could, in connection with PAPs, engage in the conduct that the Government, many years after the issuance of the SAB, now deems to be problematic. It does not address whether a manufacturer could retain or utilize third-party "hubs" to perform benefit investigation or other services. *See generally* 2005 SAB. Nor did it require, or state that compliance with the AKS required,

charities to utilize patient "wait lists," or prohibit charities from processing grant applications on a first-come, first-served basis. In fact, multiple charities explained to OIG that they would function *without* waitlists. (*See, e.g.,* SOF ¶ 71, Ex. 33.) OIG did not raise objections, and instead issued advisory opinions to charities, including CDF and TAF, without requiring certifications regarding the use or decision not to use waitlists. (SOF ¶¶ 66, 75).

The 2005 SAB also did not prohibit charities from processing grant applications transmitted in "batch files."[4] Nor did the 2005 SAB also require a charitable PAP to receive money for a particular disease state fund from more than one donor or wait for donations from multiple donors before disbursing funds. *See generally* 2005 SAB at 70627.

In May 2014, the OIG issued a Supplemental Special Advisory Bulletin on the subject of Independent Charity Patient Assistance Programs, intended to "update[] the [2005 SAB]." *See* 79 Fed. Reg. 31120 (May 30, 2014) ("2014 SSAB"). Like the 2005 SAB, the 2014 SSAB did not prohibit: (1) manufacturers from working with hubs to perform benefits investigation or other services, or charities from communicating information to hubs; (2) charities from utilizing patient wait lists or granting applications on a first-come, first-served basis; or (3) prohibit charities from processing grant applications transmitted in batch files. *See generally id.* (*See also* SOF ¶¶ 18-24.)

[4] "Batch file" refers to referrals of, or the submission of enrollment applications on behalf of, patients in "mass" via the internet, rather than individually (*e.g.*, via fax). (*See, e.g.*, SOF ¶ 12 at Ex. 4, M. Boyd Dep. 42:13-24; 70:2-71:5.) Multiple witnesses testified that batch file enrollment facilitated the efficient operation of the charities and expedited patient access to funding, and that the government's allegations are inconsistent with the actual operation of batch file enrollment. (*See, e.g.,* SOF ¶ 92(j) at Ex. 45, A. Stotts Dep. 49:10-50:9.)

### E. No Witnesses Understood Their Conduct Was Unlawful at the Time of Teva's Donations.

None of the fact witnesses deposed in this case, including those from Teva, CDF, TAF, ACS, and AssistRx, testified that they understood or were concerned that their conduct relating to Teva's patient referrals, interactions with hubs, or donations to copay assistance foundations was unlawful. In fact, the record developed through more than a dozen depositions makes clear that each witness's intent was to help ***all MS patients, including those on Copaxone***, and each believed they were acting in accordance with the law:

*Teva*. Denise Lynch, former Vice President of Patient Services and Solutions at Teva, was the person primarily responsible for recommending the amount and timing of Teva's donations until she retired in 2014. (SOF ¶ 46.) Ms. Lynch understood that Teva was not supposed to seek patient-specific data directly from a charity, but that obtaining that data from ACS was appropriate "because ACS represented only a portion of the patient population," (*id*. ¶ 92(k)). Patricia Glover (former Teva Chief Compliance Officer) testified that Teva's Legal department was "really involved" in Teva's patient assistance program and nothing Ms. Lynch told her about the donation process gave Ms. Glover a reason to believe it "potentially violated the [AKS]" or "the 2005 guidance" or that Teva was "directly or indirectly [controlling] any charity to which Teva donated," (*id*. ¶ 92(b)). Barbara Ross (former Medicare Specialist in Teva's Shared Solutions group) never believed anyone at Teva was "acting unethically" with regard to its patient referrals and charitable PAP donations, (*id*. ¶ 92(d)). Dorothy Parker (former Manager in Teva's Shared Solutions group) believed Ms. Lynch was the "most honorable person on this Earth" and "would never engage in any activity she believed to be illegal or unethical," (*id*. ¶ 92(a)). John Hassler (former Vice President of Marketing at Teva) testified that he is "not aware of any instances" in which Teva's co-pay assistance donations "would have violated"

guidance from the OIG (*id*. ¶ 92(e)). Cathy Kennedy (former Customer Information Specialist in Teva's Shared Solutions group) testified that she never had "any concerns" that the "charities … were not sufficiently independent from Teva" (*id*. ¶ 92(f)).

Even former TAF Co-Executive Director Mr. Hensley, whose affidavit is cited and relied on throughout the government's Complaint, testified that he did not believe there was anything illegal or unethical about TAF providing ACS with information that ACS in turn provided to Teva, nor did he think there was anything illegal or unethical with Teva using that information to inform its donations to TAF. (*Id*. ¶ 99.) Mr. Hensley also testified that he understood that Ms. Lynch consulted with Teva's legal and compliance teams concerning its donations:

> Q. Did you understand that Ms. Lynch consulted with people in Teva's legal and compliance department concerning Teva's donations to CDF and TAF?
>
> A. Yes, ma'am.
>
> Q. How did you know that?
>
> A. . . . They would have meetings about different programs, and they would have to get sign-off on programs, et cetera, from legal and compliance as well.
>
> …
>
> Q. And you understood that [Ms. Lynch] needed legal and compliance sign-off with regard to Teva's relationships with ACS and TAF and CDF and AssistRx?
>
> A. Yes, ma'am.

(*Id*. ¶ 93.)

***CDF***. Michael Banigan, former President of CDF, believed CDF operated consistently and "within the spirit of" guidance from OIG. (*Id*. ¶ 92(h).)

***TAF***. Edward Hensley testified that he did not think there was anything illegal or unethical with TAF providing ACS with information that Teva used to determine the amount of its donations:

> Q. Did you think there was anything illegal or unethical about Ms. Boyd [TAF] providing that number to Mr. Blanc [ACS]?
>
> A. No.
>
> Q. Did you think there was anything illegal or unethical about Mr. Blanc [ACS] providing that information to Ms. Lynch?
>
> A. No.
>
> Q. Did you think there was anything illegal or unethical if Ms. Lynch used that information to calculate a donation?
>
> A. No.

(SOF ¶ 99 (objections omitted).) Nor did Maureen Boyd, former TAF Director and Vice President, believe TAF did anything unethical or illegal with respect to its funding of copay assistance grants or its receipt of donations from Teva. (SOF ¶ 92(i).)

To the contrary, Mr. Hensley believed that Ms. Lynch was acting in the best interest of all MS patients and that donating to a charitable foundation that used batch files, among other attributes, helped all MS patients access their treatment more quickly. Among other things, Mr. Hensley testified:

> Q. Did you think it was important to Denise Lynch to see multiple sclerosis patients go on the therapies their doctors prescribed?
>
> A. Yes, ma'am.

(SOF ¶ 100 (objections omitted).)

***ACS***. Adam Stotts, former Implementation Manager at ACS, and David Blanc, former Director of Patient Assistance at ACS, did not believe Teva's dealings with ACS with regard to patient referrals, or ACS's referral of patients to charities via "batch files," to be "unethical," "improper," or a "violation of the law." (SOF ¶¶ 92(g), 92(j).)

***AssistRx***. Adam Stotts, Sr. Vice President at AssistRx, and Maureen Boyd, Vice President at AssistRx, did not believe Teva's dealings with AssistRx were unethical or illegal. (SOF ¶¶ 92(i), 92(j).)

And none of these witnesses testified that they entered into an illegal agreement. (*See generally* SOF ¶¶ 92, 93.)

## III. LEGAL STANDARD

Federal Rule of Civil Procedure 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In that situation, there is no "genuine issue as to any material fact" because "failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* The moving party bears the initial burden "to assert the absence of a genuine issue of material fact and then support that assertion by affidavits, admissions, or other materials of evidentiary quality." *Mulvihill v. Top-Flite Golf Co.*, 335 F.3d 15, 19 (1st Cir. 2003) (citation omitted). "Once the movant has done its part, the burden shifts to the summary judgment target to demonstrate that a trialworthy issue exists." *Id.* "The mere existence of a scintilla of evidence in support of the plaintiff's position is not enough to ward off summary judgment. Where the plaintiff has the burden of proof, there must be evidence on which the [factfinder] could reasonably find for the plaintiff." *Irobe v. United States Dep't of Agric.*, 890 F.3d 371, 380 (1st Cir. 2018) (internal citations and quotations omitted).

Expert opinions that depend on "conclusory assertions, unsupported by specific facts made in affidavits opposing a motion for summary judgment, are not sufficient to defeat a

motion for summary judgment." *Thomas v. Christ Hosp. & Med. Ctr.*, 328 F.3d 890, 894 (7th Cir. 2003); *see also Hayes v. Douglas Dynamics*, 8 F.3d 88, 92 (1st Cir. 1993) (affirming grant of summary judgment where expert opinion failed to demonstrate causation).

The government contends that Teva violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733 by violating the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a–7b.[5] The AKS prohibits individuals or entities, *inter alia,* from knowingly and willfully paying "remuneration" in order to induce or reward the referral of business reimbursable under Federal health care programs, including Medicare. *See* 42 U.S.C. § 1320a-7b(b)(2)(B).

## IV. ARGUMENT

### A. There is No Evidence That Teva's Donations and Patient Referrals to Hubs Caused Any Particular False Claims.

#### 1. The Government Must Prove "But-For" Causation.

To prove a false claim predicated on an alleged AKS violation, the government must provide competent evidence that the claim includes items "***resulting from*** [the alleged AKS] violation." 42 U.S.C. § 1320a-7b(g) (emphasis added). The "resulting from" causation requirement derives from the 2010 amendments to the AKS, which provide that "a claim that includes items or services ***resulting from*** a violation of [the AKS] constitutes a false or fraudulent claim for purposes" of the FCA. *Id.*

The AKS does not define the statutory phrase "resulting from," so a court must "give it

[5] The FCA's presentment clause, 31 U.S.C. § 3729(a)(1)(A), is violated when any person presents, or causes to be presented, "false or fraudulent claim[s] for payment or approval" to the federal government. *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016). The FCA's false records clause, 31 U.S.C. § 3729(a)(1)(B), is violated when any person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *U.S. ex rel. D'Agostino v. EV3, Inc.*, 153 F. Supp. 3d 519, 530 (D. Mass. 2015), *aff'd sub nom. D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). The FCA's conspiracy clause, 31 U.S.C. § 3729(a)(1)(C), is violated when any person conspires to commit a violation of the FCA. *Id.*

its ordinary meaning." *See Burrage v. United States*, 571 U.S. 204, 210 (2014) (interpreting the phrase "resulting from" in the Controlled Substances Act); *Penobscot Nation v. Frey*, 3 F.4th 484, 491 (1st Cir. 2021) (en banc) (concluding that where a statute contains "an undefined term, we 'construe it in accordance with its ordinary meaning'") (citations omitted)).

In *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834 (8th Cir. 2022), the Eighth Circuit "ha[d] little trouble concluding that, in common and ordinary usage, the participle phrase 'resulting from' … expresses 'a but-for causal relationship.'" *Cairns*, 42 F.4th at 834. Applying this conclusion in the context of a false claim premised on an AKS violation, the *Cairns* court held that "but-for" causation requires proof that the claims "***would not have included particular*** '***items*** or services' ***absent*** the illegal kickbacks." *Id.* at 835 (emphasis added); *see also Comcast Corp. v. Nat'l Ass'n of Afr. Am.-Owned Media*, 140 S. Ct. 1009, 1014 (2020) (underscoring that but-for causation is the default rule against which Congress legislates).

Last month, the Sixth Circuit reached the same conclusion in *U.S. ex rel. Martin v. Hathaway*, No. 22-1463, --- F.4th ---, 2023 U.S. App. LEXIS 7319, *20-25 (6th Cir. Mar. 28, 2023). In *Martin*, the Sixth Circuit rejected the government's contention that but-for causation is inconsistent with the legislative history of the amendments to the AKS. *See id.* The *Martin* court declined to follow the now-minority approach from the Third Circuit, *United States v. Greenfield Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018), because *Greenfield* failed to construe the AKS amendments in accordance with the plain language of the statute and the rule of lenity. As the *Martin* court explained: "[W]e generally do not consider legislative history in construing a statute with criminal applications, the idea being that no one should be imprisoned based on a document or statement that never received the full support of Congress and was presented to the President for signature." *Martin*, 2023 U.S. App. LEXIS 7319, at *25 (citation

omitted); *see also Cairns*, 42 F.4th at 836 ("[I]t is our job to interpret Congress's actual words.").

Although the First Circuit has not directly ruled on the standard of causation for AKS-based false claims, the holdings in *Cairns* and *Martin* are consistent with the First Circuit's opinion in *Guilfoile v. Shields*. In *Guilfoile*, the First Circuit concluded that a complaint plausibly alleged "a sufficient causal connection" where the Court could "reasonably infer … that [the healthcare company] paid [a consultant] to induce him" and that "***if not*** for the agreement with [the consultant], [the healthcare company] would not have been in a position to benefit from federal health care payments . . . ." *Guilfoile*, 913 F.3d at 190 (emphasis added).[6] Further, the "but-for" standard of causation under the AKS is not only required by the plain text of the statute, it is also consistent with the causation required under the FCA. *See, e.g.*, *U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, No. 96-cv-11651, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003) (discussing common law concepts of causation).

This Court should likewise hold that that the plain text of the AKS requires proof of "but-for" causation—*i.e.*, the government must prove that the claims at issue "would not have included ***particular*** 'items or services' absent the illegal kickbacks." *Cairns*, 42 F.4th at 835 (emphasis added). And here, "[t]here's ***not one claim for reimbursement identified*** with particularity in this case ***that would not have occurred anyway***, no matter whether the

[6] The First Circuit did not "attempt to assess the full implications of the AKS provision[.]" *Id.* While the *Guilfoile* court cited the now minority position of Greenfield and the district court opinion in *U.S. ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601-IT, 2018 U.S. Dist. LEXIS 70848 (D. Mass. Apr. 27, 2018), it did not adopt their reasoning or address the scope of the "resulting from" requirement. In addition, Judge Barron noted that the AKS "does not have limitless reach." *Guilfoile*, 913 F.3d at 199 (Barron, J. concurring in part and dissenting in part). Rather, "conduct that lies outside even the periphery—**as measured, most clearly, by the words that Congress chose to denominate the statute's bounds**—is not conduct that may give rise to liability." *Id.* (emphasis added). Thus, this Court should not be guided by prior decisions that did follow the plain language of the statute.

underlying [conduct] occurred or not." *Id.* (emphasis added); *see also Martin*, 2023 U.S. App. LEXIS 7319, at *22.

Even under the nebulous "link" standard in *Greenfield*, the court granted summary judgment in favor of the defendant where "the evidence does not link [the] alleged kickback scheme to ***any particular claim***." *Greenfield*, 880 F.3d at 99-100; *see also id.* ("plaintiffs must provide evidence of ***at least one false claim*** to prevail on summary judgment") (emphases added). Under any standard, "[i]t is not enough . . . to show temporal proximity between [the] alleged kickback plot and the submission of claims for reimbursement." *Id.*

**2. The Government Cannot Prove "But-For" Causation.**

The government has failed to adduce evidence that, but for Teva's donations to CDF and TAF, any claims submitted to Medicare for Copaxone that were funded by CDF or TAF would not have otherwise been submitted for reimbursement. There is no testimony from physicians or patients who would not have sought Medicare reimbursement for Copaxone in the absence of Teva's donations. (SOF ¶¶ 104-106.) The government's experts concede that they did not attempt to create econometric models or survey Medicare beneficiaries who received patient assistance to test whether any, all, or a portion would have discontinued their medically necessary prescriptions for Copaxone absent the alleged kickbacks. (SOF ¶¶ 102-104.)

In the absence of any evidence of "but for" causation, the government presents expert testimony that high patient cost sharing ***generally*** tends to decrease medication utilization—and therefore some unknown portion of the patients who received charitable assistance ***may*** have discontinued Copaxone use absent charitable support. (*See, e.g.,* SOF ¶ 102 at Ex. 55.) They have also presented three categories of estimates for the government's expenditures on

Copaxone.[7] But by the experts' own admissions, none of this evidence satisfies the "essential element" of what "particular" claims would not have been submitted "absent" the alleged AKS violations. *See Cairns*, 42 F.4th at 835 ("Causation is an 'essential element[]' that must be proven, not presumed.").

First, Dr. Ellis and Prof. Dafny each stated that they did ***not*** attempt to demonstrate a causal relationship between Teva's donations and particular claims for reimbursement because counsel instructed them that such a showing of proof was not required. (*Id*. ¶¶ 103, 104.) Second, the opinions that they do present are insufficient to allow a fact finder to conclude that any particular claim would not have been submitted absent Teva's donations. Prof. Dafny opines that increased patient cost sharing, as a general matter, tends to decrease product utilization, but she does not provide any evidence or testimony "regarding the effects of Teva's donations or contributions on the use of Copaxone." (SOF ¶ 102 at Exs. 54-56.)

Meanwhile, Dr. Ellis concedes that the correlation analyses that he performed do not establish a causal relationship between donations and Medicare expenditures. (*See* SOF ¶ 102 at Ex. 52, 1/23/23 P. Ellis Dep. 34:20-35:5.) Rather, he offers the conclusory opinion that based on a general understanding of the economic literature, "many of the affected patients (though by no means all of them) would have stopped taking the drugs involved or would have never started

[7] This includes: (1) a general "matching" exercise of all (or nearly all) Copaxone Medicare reimbursement claims that bear some relation to CDF or TAF disbursements; (2) Medicare reimbursements for "mid-year" enrollees in CDF and TAF who took Copaxone; and (3) Medicare reimbursements for patients who received free product from Teva prior to receiving charitable assistance. (SOF ¶ 102 at Ex. 51, Dew Rebuttal Rpt., Ex. 52, P. Ellis Rebuttal Rpt.) While this may create an inference that Teva's donations could at least in part have *supported* Copaxone, it does not say anything about whether any patient would not have used the Copaxone they were prescribed but for the donation. On the contrary, Mr. Dew and Dr. Ellis do not offer any opinion that the reimbursements were caused by Teva's donations. (SOF ¶ 102 at Ex. 51 at 3; Ex. 49 at 39:22-40:15; Ex. 53 at 19:19-20:6.) Moreover, according to the government's own experts, Teva was not the sole contributor to CDF's MS fund in any of the analyzed years, and was the only contributor to TAF's in just one. (SOF ¶ 102 at Ex. 29 at 39.)

taking them in the first place, absent the assistance they received." (SOF ¶ 102 at Ex. 29.) He did not (and by his own admission cannot) quantify what he means by "many" patients and refused to testify whether "many" is 5%, 95%, or somewhere in between. (SOF ¶ 102 at Ex. 53.)

Even fully crediting the testimony of the government's experts, Dr. Ellis's concession that "by no means all" of the patients who received assistance would have discontinued Copaxone—without any attempt to specify ***which*** patients or ***how many***—demonstrates the government's lack of evidence on the essential causation element, and summary judgment should therefore be granted. Rather, for each and every claim at issue in this case (either before the 2010 AKS Amendments or after), the government's position suggests that causation may be presumed for kickback "tainted" claims. There is no support for the government's position on causation in either the text of the statute or First Circuit case law. *See U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, No. CV 21-11627-FDS, 2022 WL 17417577, at *18 (D. Mass. Dec. 5, 2022) (Saylor, C.J.) ("[I]t would not be irrational to conclude that the presence of kickbacks taints the entire payment process, so that 100% of the claims may be deemed to have been caused by the violation. No published case in the First Circuit, however, has ever gone so far."); *Cairns*, 42 F.4th 836 ("Although the government might have preferred one of these other [alternative standards of causation], it is our job to interpret Congress's actual words.").

* * *

"The summary judgment stage is 'the put up or shut up moment in litigation.'" *Jakobiec v. Merrill Lynch Life Ins. Co.*, 711 F.3d 217, 226 (1st Cir. 2013) (quotation omitted). There is no evidence in the record that shows which Medicare beneficiaries who received reimbursements for Copaxone would not have used the medically necessary medication prescribed to them ***in the absence*** of Teva's donations. The government cannot identify even a single prescription

submitted by a particular person and present any non-speculative evidence that the prescription would not have been submitted to Medicare for reimbursement in the absence of Teva's donations. The reason is simple: this is not a case that involves any medically unnecessary treatment. Teva's donations simply made it easier for patients to access the medication that a doctor had already prescribed. In the absence of such evidence, summary judgment should be granted. *See Martin*, 2023 U.S. App. LEXIS 7319, at *24 (physicians' choices "doom the chain of causation"); *see also id.* at *26-27 ("A faithful interpretation of the … 'resulting from' requirement[] still leaves plenty of room to target genuine corruption. . . . So long as proof exists that the referrals would not have been made without the remuneration, and that claims would not have been submitted to the government without those referrals, causation for [FCA] lawsuits would be satisfied too.").

### B. Teva Did Not Knowingly Violate the False Claims Act or Willfully Violate the Anti-Kickback Statute.

Teva could not act with the requisite scienter. The FCA restricts liability to defendants proven to have caused the submission of a materially false claim with "actual knowledge," "deliberate ignorance," or "reckless disregard of the … falsity of the information." 31 U.S.C. §3729(b)(1)(A). The AKS further restricts liability only to those who act "willfully," *i.e.*, those who act "purposely, with the intent to violate the law, to do something purposely that law forbids." *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 33 (1st Cir. 1989); 42 U.S.C. § 1320a-7b(b)(2)(B).

In *Safeco Insurance Co. of America v. Burr*, the Supreme Court held that when a defendant's interpretation of an ambiguous statutory provision is objectively reasonable, the defendant's conduct is not in "reckless disregard[.]" *See* 551 U.S. 47, 70 n.20 (2007). Every circuit court that has considered *Safeco* in the context of legally false claims has applied it to the

FCA's reckless disregard standard.[8] Although the First Circuit has not directly addressed the application of *Safeco* to the FCA, other circuits have held that a defense to FCA liability based on a reasonable interpretation of a statute includes three inquiries: "(1) whether the relevant statute was ambiguous; (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and (3) whether a defendant was 'warned away' from that interpretation by available administrative and judicial guidance." *United States v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018) (citing *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015)).

**1. The AKS and OIG Guidance are Ambiguous.**

The 2005 SAB is ambiguous in several important respects. First, it allows for single donor and single drug funds. 70 Fed. Reg. 70623, 70624 n. 3. The 2014 SSAB allows the same. 79 Fed. Reg. 31120, 31122. Under such circumstances, a manufacturer would necessarily ***know and intend*** that each dollar donated to a charity would benefit a patient taking its product. (SOF ¶ 25.) Therefore, it cannot be reasonably said that knowledge and intent to benefit one's own patient population is enough to give rise to AKS liability. Indeed, the primary drafter of the 2014 SSAB made the startling admission that [redacted]

[8] *See, e.g.*, *U.S. ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455 (7th Cir. 2021) ("There is no reason why the scienter standard established in *Safeco* (for violations committed knowingly or with reckless disregard) should not apply to the same common law terms used in the FCA."); *U.S. ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649, 658 (7th Cir. 2022) (similar); *United States v. Allergan, Inc.*, 746 F. App'x 101 (3d Cir. 2018); *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879 (8th Cir. 2016); *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1178 (9th Cir. 2016). The Supreme Court granted certiorari in *SuperValu* and *Safeway* to address whether evidence of a defendant's subjective belief that conduct is unlawful is relevant to the question of scienter under the FCA. *See U.S. ex rel. Schutte v. SuperValu Inc.*, No. 21-1326 (U.S.). Regardless of how the Court rules in *SuperValu*, there is no evidence that anyone from Teva subjectively believed their conduct was unlawful.

[redacted]. (*Id.*) It is thus ambiguous exactly *what* intent would violate the AKS based on the 2005 SAB or the 2014 SSAB.[9]

Second, the SAB does not define what *conduct* would or would not violate the AKS; rather, the SAB includes factors that "should" raise "few, if any" concerns regarding the AKS. These factors, in turn, are subject to multiple distinct, reasonable interpretations. For example, the 2005 SAB advises that a properly structured program would be one in which "the pharmaceutical manufacturers does not solicit or receive data ***from the charity***[.]" 70 Fed. Reg. 70623, 70626 (emphasis added). To the extent the government argues the 2005 SAB was meant to apply to other entities beyond the "charit[ies]," it is ambiguous. In addition, the 2005 SAB requires the charity to award assistance in a "truly independent manner," which is qualified by a limiting phrase: "*i.e.*, the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer[.]" *Id.* at 70626. Thus, the plain language of the SAB provides that a manufacturer acts in a truly independent manner so long as the assistance cannot be attributed to the manufacturer.[10]

Third, the 2005 SAB observes that: "[the] PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." *Id.* at 70627. It is undisputed that the charities maintained the

[9] Teva's Objections regarding Teva's Motion to Compel Internal HHS-OIG Communications remain pending. *See* ECF No. 145. Given the unresolved state of those objections, [redacted], the summary judgment record should remain open pending resolution of these issues.

[10] The government's position appears to ask the Court to ignore the plain language and interpret this phrase as providing merely an example of what qualifies as "truly independent." But "*i.e.*" (an abbreviation of the Latin phrase "*id est*") is used as a limiting phrase meaning "that is," whereas "*e.g.*" (an abbreviation of the Latin phrase "*exempli gratia*") means "for example." *Otter Prod., LLC v. Treefrog Devs. Inc*., 2012 WL 4468211, at *22 n. 12 (D. Colo. Sept. 27, 2012) (explaining that use of *i.e.* is a "further clarification" of the preceding word or phrase, whereas "e.g." signifies "but one example of how the word . . . is being used.").

ultimate control in the distribution of funds, as even Mr. Hensley testified. (SOF ¶¶ 58, 85.) There is no evidence that Teva's donations impacted any patient's drug choices, particularly where each patient who received foundation support already had been prescribed a DMT. (*See, e.g.*, SOF ¶¶ 92(b), 105-106.; *see also id*. ¶ 86 at Ex. 31 ¶ 8.)

Furthermore, the mere fact that the OIG found it necessary to issue a second advisory bulletin on the same issues in 2014 conclusively evidences that the 2005 SAB was ambiguous. The 2014 SSAB acknowledges that, because the 2005 SAB was issued before Medicare Part D went into effect, the 2005 SAB could only "speculate on fraud and abuse areas[.]" *See* 79 Fed. Reg. 31120 (May 30, 2014). The 2014 SSAB states that it does not replace the 2005 SAB, but rather clarifies how it applies based on "experience [the OIG has] gained in the intervening years." *Id.* Furthermore, the OIG itself acknowledges in the 2014 SSAB that prior guidance and advisory opinions ***did not address conduct of donors***. *See* 79 Fed. Reg. 31120, 31123. ("[W]hen we have issued favorable advisory opinions regarding Independent Charity PAPs, the focus has been on the charities that requested the opinions—***not the donors***.") (emphasis added). And the 2014 SAB remained silent with regard to the use of hubs, batch files, and first-come/first-served application processes to facilitate enrollment. *See id.*

**2. Teva Acted Consistently with a Reasonable Interpretation of the OIG Guidance.**

In the face of this ambiguous guidance, Teva acted consistently with an objectively reasonable interpretation of the law and no witness acted with the intent to violate the law. Every Teva employee who was asked—including Teva's former Chief Compliance Officer—testified that they did not believe or understand that Teva's conduct violated any aspect of the relevant OIG guidance. (*See, e.g.,* SOF ¶ 92(a)-(f), (k).) Accordingly, Teva could not have acted

either "willfully" under the meaning of the AKS or with "reckless disregard" to the legal falsity of claims within the meaning of the FCA.

The reasonableness of Teva's interpretation of the OIG guidance is further evidenced by the fact that it arrived at its interpretation through sound legal advice. Relevant Teva personnel routinely sought advice from attorneys so as not to violate the law. (*Id.* ¶ 93.)[11]

**3. No Authoritative Guidance Warned Teva Away From Its Interpretation.**

Finally, Teva was not "warned away" by any authoritative guidance. During the relevant time period, no courts addressed what was and was not permissible under either the 2005 or 2014 SABs. The ***only*** court opinion undersigned counsel is aware of during the relevant time period that addressed the types of issues in this case held that a pharmaceutical manufacturer "***cannot be liable*** for giving money to co-pay foundations" where, as here, the plaintiff failed to show "that these ***donations were contingent on the foundation's agreement to purchase or recommend*** [the manufacturer's] drugs." *See United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016) (emphasis added). In *Celgene*, as in this case, the manufacturer donor "gave tens of millions of dollars per year to non-profit organizations for the purpose of helping patients (including those enrolled in Medicare) pay for ten different drugs treating the disease state including three of which were manufactured by [the defendant]." *Id.* Absent

[11] For similar reasons, the government cannot prove a conspiracy to violate the FCA. *See U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009); *U.S. ex rel. Lisitza v. Par Pharm. Companies, Inc.*, 276 F. Supp. 3d 779, 808–09 (N.D. Ill. 2017) (granting summary judgment for defendant where, despite evidence of agreement to engage "prescription-switching" scheme, record contained insufficient evidence of agreement to present false claims in violation of the FCA); *U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343–44 (5th Cir. 2008) (granting summary judgment for defendant on FCA conspiracy claim where plaintiff failed to prove "existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid" by the government).

evidence that donations were contingent on the charity's promotion or purchase of the manufacturer's product, summary judgment was granted in favor of the manufacturer. *See id.*

While this court has since disagreed with the *Celgene* court's statement of the law, *United States v. Teva Pharm. USA, Inc.*, 560 F. Supp. 3d 412, 420 (D. Mass. 2021), the *Celgene* court's decision is consistent with an objectively reasonable view of the OIG SABs that regardless of whether a manufacturer works in conjunction with a hub to refer patients to a charity near in time to a manufacturer's donations, donations to a *bona fide*, independent charity "sever the nexus" between the subsidies and the manufacturer. 70 Fed. Reg. 70623, 70624 n. 3.

Consistent with this interpretation, when Teva's CCO communicated about Teva's donations process with Ms. Lynch, Teva's CCO did not have any concerns. (SOF ¶ 92(b).) Moreover, when Teva's Legal and Compliance functions became aware that certain conduct could raise AKS risks, they took steps to ensure compliance with the law and to reduce those risks. For instance, Teva ***stopped donating*** to CDF when it was reported that CDF had been "earmarking" donors' "dollars for [another] company's patients," which Teva understood was prohibited under the 2005 SAB. (SOF ¶ 68.) Teva also recognized that that OIG addressed the conduct of manufacturer donors for the first time in the 2014 SSAB. (*See* SOF ¶ 96.) Teva adjusted its practices in response to those changes. (*Id*., at Ex. 30 at 211:24-212:11 (stating Teva changed the review, approval, and submission process for donations and instructed team to stop receiving aggregated patient referral data from hub); 114:3-4 ("the 2015 guidance . . . ***now*** put responsibility on the manufacturers"); *see also id*. at Ex. 13 at 70:03 – 71:20 (testifying decision to stop analyzing financial benefit was designed to maintain "good compliance standards," not because Teva violated any rules).) It would be incongruous to find that Teva's employees

knowingly and willfully violated the law by reaching the same conclusion that a federal court reached in 2016 in *Celgene*.

At bottom, there can be no genuine dispute that Teva reasonably understood that its donations to CDF and TAF were consistent with objectively reasonable interpretations of the OIG SABs, Teva actively took steps to comply with the law, no witness has testified that s/he understood their conduct was unlawful at the time, and no authoritative guidance warned Teva away from its interpretation.[12] To the contrary, the record is replete with evidence that Teva acted consistently with a reasonable interpretation of ambiguous OIG SABs and summary judgment should therefore be granted.

### C. The FCA's Statute of Repose Bars Claims Accruing Before April 13, 2008.

The FCA requires that the complaint must be filed within six years of the submission of the false claim, or within three years of the date when the government learns, or should have learned, about the underlying conduct, with an absolute cut-off date—a statute of repose—of 10 years after the violation. 31 U.S.C. § 3731. Teva signed a tolling agreement with DOJ on April 13, 2018. (SOF ¶ 108.) Accordingly, at a minimum, any claims that accrued before April 13, 2008 are barred under the FCA's 10-year statute of repose.

## V. CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court enter summary judgment in favor of Defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc on all counts.

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[12] This includes witnesses from CDF, TAF, ACS and AssistRx, with whom the government alleges that Teva conspired to violate the AKS. (*See* SOF ¶¶ 91(g), 92(g)-(j).) A person cannot conspire to violate the FCA if he or she has an objectively reasonable belief that his or her conduct is legal and ethical, where "[t]he object of the conspiracy must be to make false or fraudulent claims." *Lisitza*, 276 F. Supp. 3d at 808.

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Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing document was served upon all counsel of record via ECF filing on April 24, 2023.

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